

REMARKS / ARGUMENTS

In the Final Office Action of December 3, 2009, claims 1-6 and 9-17 remain rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. The Examiner has incorporated by reference the reasons set forth in the March 31, 2009 office action. In that office action, it was the position of the Examiner that for both the elected species, (S)-2-Amino-3-methyl-butyric acid (1S,2S,4S)-2-amino-1-[(S)-2-(2-carbamoyl-2-methyl-propylcarbamoyl)-3-methyl-butyl]-4-[4-methoxy-3-(3-methoxy-propoxy)-benzyl]-5-methyl-hexyl ester, hereinafter "ES", and for compounds of formula (IB), the specification provides several example syntheses but such examples do not disclose a starting material that is known or commercially available.

In the amendment submitted in response to the March 31, 2009 office action, claim 5 was amended to indicate a compound of formula IC rather than IB because designation of formula IB for the compound recited in claim 5 was a clerical error.

It was also respectfully submitted in the March 31, 2009, amendment that the specification of the application is replete with information on the synthesis of a compound of formula I, using publicly available starting materials. With respect to the synthesis of ES, Applicants directed the Examiner to paragraphs [0138] to [0146] of the published application, Pub. No. US 2007/0142475, where the synthesis of ES is set forth using publicly available starting materials.

In the office action of December 3, 2009, the Examiner has asserted that after carefully reviewing paragraphs [0138] to [0146], it cannot be ascertained how the synthesis is carried out from commercially available or known products. The Examiner has requested Applicant's help in pointing to where such synthesis may be found.

In response, Applicants respectfully submit that the synthetic procedures required for obtaining the starting compounds as identified in the present application are synthetic procedures already well known and established in the art in connection with renin inhibitors having a structure similar to the structure of the compounds in accordance with the present invention. For example, International publication WO 02/40007, on page 2, refers to the description of aliskiren and cites European patent application EP 678503. This European patent

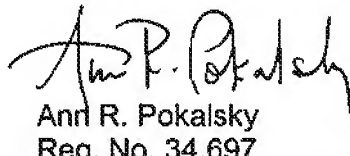
application has various US equivalents, including US 5,654,445. Both WO 02/40007 and US 5,654,445 are provided herewith, as Exhibits A and B respectively.

In US Patent 5,654,445 (Exhibit B), a synthetic procedure is described for obtaining compounds having an azido moiety as required for the starting compound. See column 19 *et seq.* Thus, at the time the present application was first filed, one skilled in the art could have obtained the starting compounds using prior art teachings an basic organic synthetic chemistry. In addition, column 19 *et seq.* of the '445 patent also provides sufficient information to make the various compounds encompassed by Applicants' generic structure in addition to ES.

Further, Dondoni et al. (*Tetrahedron Letters*, 2001,42:4819-4823), cited by the Examiner in the March 31, 2009 office action, discloses the principal synthesis necessary for obtaining a skeleton in accordance with the compounds of the present invention. The only synthetic reaction required when starting from compound I of Dondoni et al. and wishing to arrive at the designated starting compound disclosed in the present application would be a conversion of the nitrogen-containing moiety at position 5 to an azido moiety, a chemical reaction well within the usual routine of any average skilled artisan.

In view of the foregoing remarks and exhibits submitted herewith, it is respectfully submitted that the present application is in condition for allowance, which action is earnestly solicited.

Respectfully submitted,


Ann R. Pokalsky
Reg. No. 34,697
Attorney for Applicants

DILWORTH & BARRESE
1000 Woodbury Road, Suite 405
Woodbury, New York 11797
(516) 228-8484
ARP/ml